REMARKS

The present invention relates to stents with a link geometry for improved flexibility. In the Office Action dated August 14, 2002, the Examiner rejected claims 1, 2, 11, 14-16 as anticipated by Ogi, *et al.* ("Ogi"). Claims 1, 2, 7-11, and 14-16 were rejected as obvious over Penn, *et al.* ("Penn") in view of Ogi. Claims 3-6 were rejected as obvious over Ogi, and claims 12, 13, 17-25, 27-31 and 34-35 were rejected as obvious over Penn, in view of Ogi and further in view of Ley, *et al.* ("Ley") Claims 26, 32, and 33 were rejected as obvious over Penn in view of Ogi, Ley, and Rolando. The Examiner noted that claim 21 was allowable, but objected to as being dependent upon a rejected base claim.

Applicants have canceled claims 7 and 30. Therefore, claims 1-6, 8-29, and 31-35 are pending in the case.

Applicants have amended the specification to correct certain informalities with the original application. In addition, for clarity, Applicants have added metric conversions to dimensions provided in inches. Applicants have also provided temperatures in both Fahrenheit and Centigrade. Applicants have included revised drawing sheet 6 (of 7), with a revision to Figure 16. The letter "A," as identified on page 12, line 19 of the specification has been added to Figure 16. On page 18, line 22 of the specification, 1350° F has been changed to 135°. Applicants respectfully submit that one of ordinary

skill would have recognized and understood the need for these changes upon reading the original specification and upon reviewing the original drawings. Therefore, Applicants submit that no new matter has been added to the Application.

Applicants have amended independent claims 1, 17, and 27 to distinguish the present invention from the prior art. The Examiner relied on Figure 5b of Ogi as a reference that discloses Applicants' link that includes a bounded aperture disposed in the link between the cylindrical rings of the stent. The aperture in "leaf-spring like member 38b" of Ogi is nested within the peaks and valleys of the cylindrical rings of the stent equidistant from the ends of adjacent rings. This positioning limits or impairs the crimping of the Ogi stent on a delivery device, such as a catheter or balloon catheter. Because of the location and configuration of the spring bridge 38b in Ogi, the struts of undulating member 15, 25 (Ogi, Fig. 5b) cannot be completely compressed against each other during crimping because of the interference of the spring bridge 38b. As amended, independent claims 1, 17, and 27 of the present invention now provide that the aperture is nearer the end of one of the rings, so that the mounting or crimping of the stent is not impaired. This configuration provides a distinct advantage over Ogi, or any combination of Ogi, Penn, or Ley. In particular, the present invention allows the stent to be more tightly crimped onto a delivery device. This configuration allows for a narrower stent profile during delivery, which is a desirable feature.

The present application supports Applicants' amendment. The paragraph beginning on page 10, line 20 of the specification describes U-, Y-, and W-shaped portions of the ring, which are also depicted in Figures 5-7. As can be seen in Figure 15, the bounded aperture is located in the W-shaped portion of the ring. Independent claim 27 explicitly claims the bounded apertures as being located in the W-shaped portions, which places the bounded apertures nearer the end of one of the two adjacent rings. Independent claims 1 and 17 also have been amended to distinguish how the present invention does not impair the mounting of the stent on the delivery device. Those claims are, however, written more broadly than claim 27. They require that the bounded apertures be nearer the end of one ring to avoid impairment of the stent mounting. They do not, however, require U-, Y- and W-shaped portions.

In view of the differences between the present invention and the various combinations of Penn, Ogi, and Ley cited by the Examiner, Applicants respectfully submit that independent claims 1, 17, and 27 are allowable over the prior art. Therefore, Applicants believe that the claims depending from independent claims 1, 17, and 27 are also allowable.

As indicated in the office action, dependent claim 21 contains allowable subject matter. Claim 21 has been rewritten in independent form and contains all of the

limitations of the base claim and all of the claims from which it depended. Therefore, Applicants submit that claim 21 is now in condition for allowance.

In conclusion, Applicants submit that claims 1-6, 8-29, and 31-35 are in condition for allowance. Reconsideration and reexamination are requested and a prompt Notice of Allowance is respectfully solicited.

Should the Examiner have any questions, kindly telephone the undersigned. Applicants believe that in view of the present amendment, no additional fees are required. Should additional fees be necessary, the Commissioner is authorized to charge any additional fees that may be required by this paper to Deposit Account No. 06-2425.

Attached to this Amendment is a marked-up version of the changes made to the claims by the present Amendment. The attached page is captioned "Version With Markings To Show Changes Made."

Respectfully submitted,

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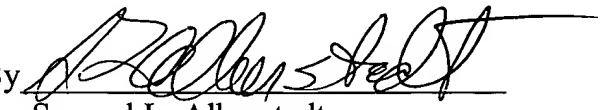
By 
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VERSION WITH MARKINGS TO SHOW CHANGES

IN THE SPECIFICATION:

Please enter the following substitute paragraph for the specification at page 2, line 1, as follows:

The stent of the present invention generally includes a plurality of cylindrical elements that are interconnected to form the stent. The stent typically is mounted on a balloon catheter if it is balloon expandable, or else it is [or] mounted on a catheter without a balloon if it is self-expanding.

Please enter the following substitute paragraph for the specification at page 5, line 19 as follows:

FIG. 11 is a cross-sectional view [strut] of the stent strut.

Please enter the following substitute paragraph for the specification at page 5, line 20 as follows:

FIG. 12 is a cross-sectional view of [the] a wider stent strut.

Please enter the following substitute paragraph for the specification at page 10, line 20 as follows:

Referring to FIGS. 5-7, the stent of the invention can be described as having cylindrical rings formed of U-shaped portions 90, Y-shaped portions 92, and W-shaped portions 94. Again, while the stent is generally laser cut from a solid tube and it typically has no [discreet] discrete parts, for ease of identification the stent of the invention also can be referred to as having U-, Y-, and W-shaped portions. The U-shaped portions have [not] no supporting structure attached thereto. The Y-shaped portions, at their base, or apex, have arm 68 extending therefrom and attached to undulating link 54. The W portion has at its base or curve portion arm 69 which attaches at the other end of the undulating link. The length of the arms attaching the links to the rings can vary. Importantly, the arms should be sized in conjunction with the undulating link so that the link is properly positioned in the W-shaped portion. Preferably, undulating link 54 is contained within W-shaped portion 94, which should be wide enough to accommodate the undulating link when the stent is crimped so that no portion of the undulating link and the W-portion overlap. Preferably, the undulating link and the W-shaped portion are in the same cylindrical plane 50 as defined by the cylindrical outer wall surface 52 and the cylindrical inner wall surface 53.

Please enter the following substitute paragraph for the specification at page 11, line 17 as follows:

In one aspect of the invention, the stent is formed so that the struts 98 (FIG. 13) have variable thickness (not shown) along the stent length. As one example, it is contemplated that struts 104 at the ends of the stent may be radially thicker than the struts 106 in the center of the stent for purposes for radiopacity and to counter balloon expansion. When the balloon first inflates, the balloon ends have a tendency to inflate at a faster rate than the balloon center, however, with thicker struts at the stent ends the balloon, and hence the stent, will expand more uniformly.

Please enter the following substitute paragraph for the specification at page 12, line 20 as follows:

FIGS. 17 and18 are conceptually similar to FIGS. 15 [AND] and 16. The stent 310 comprises a plurality of cylindrical rings 340 connected by links 354. Apertures 380 are elliptically shaped with the major axis of the ellipse running perpendicular to the stent's longitudinal axis. In other words, the long part of the ellipse 382 is perpendicular to the longitudinal axis, and the short elliptical part 384 is parallel. The link 354 also includes tapered portion 385 and radius portion 387. The structural portion surrounding the elliptical aperture 380 responds to stress in much the same way as the rectangular

structure in FIG 16. As the ellipse is stretched in tension it becomes more circular and less elliptical. As the ellipse is placed in compression, it becomes more elliptical, approaching the shape of a thin rectangle, a slit, or even two separate rounded apertures separated by a contact point.

Please enter the following substitute paragraph for the specification at page 14, line 11 as follows:

The tubing may be made of suitable biocompatible material such as stainless steel or another metal alloy. The stainless steel tube may be Alloy type: 316L SS, Special Chemistry per ASTM F138-92 or ASTM F139-92 grade 2. Special Chemistry of type 316L per ASTM F138-92 or ASTM F139-92 Stainless Steel for Surgical Implants in weight percent.

Carbon (C)	0.03% max.
Manganese (Mn)	2.00% max.
Phosphorous (P)	0.025% max.
Sulphur (S)	0.010% max.
Silicon (Si)	0.75% max.
Chromium (Cr)	17.00-19.00%

Nickel (Ni)	13.00-15.50%
Molybdenum (Mo)	2.00-3.00%
Nitrogen (N)	0.10% max.
Copper (Cu)	0.50% max.
Iron (Fe)	Balance

The stent diameter is very small, so the tubing from which it is made must necessarily also have a small diameter. Typically the stent has an outer diameter on the order of about 0.06 inch (1.524 mm) in the unexpanded condition, the same outer diameter of the tubing from which it is made, and can be expanded to an outer diameter of 0.1 inch (2.54 mm) or more. The wall thickness of the tubing is about 0.003 inch (0.0762 mm).

Please enter the following substitute paragraph for the specification at page 15, line 15 as follows:

Cutting a fine structure (0.0035["] inches or 0.0889 mm web width) requires minimal heat input and the ability to manipulate the tube with precision. It is also necessary to support the tube yet not allow the stent structure to distort during the cutting operation. In order to successfully achieve the desired end results, the entire system must be configured very carefully. The tubes are made typically of stainless steel with an

outside diameter of 0.060["] to 0.066["] inches (1.524-1.676 mm) and a wall thickness of 0.002["] to 0.004["] inches (0.0508-0.1016 mm). These tubes are fixtured under a laser and positioned utilizing CNC equipment to generate a very intricate and precise pattern. Due to the thin wall and the small geometry of the stent pattern (0.0035["] inches or 0.0889 mm typical web width), it is necessary to have very precise control of the laser, its power level, the focused spot size, and the precise positioning of the laser cutting path.

Please enter the following substitute paragraph for the specification at page 16, line 26, through page 17 line 12 as follows:

In addition to the laser and the CNC positioning equipment, the optical delivery system includes a beam expander to increase the laser beam diameter, a circular polarizer, typically in the form of a quarter wave plate, to eliminate polarization effects in metal cutting, provisions for a spatial filter, a binocular viewing head and focusing lens, and a coaxial gas jet that provides for the introduction of a gas stream that surrounds the focused beam and is directed along the beam axis. The coaxial gas jet nozzle (0.018["] inches or 0.4572 mm I.D.) is centered around the focused beam with approximately 0.010["] inches (0.254 mm) between the tip of the nozzle and the tubing. The jet is pressurized with oxygen at 20 psi and is directed at the tube with the focused laser beam exiting the tip of the nozzle (0.018["] inches or 0.4572 mm dia.). The oxygen reacts with

the metal to assist in the cutting process very similar to oxyacetylene cutting. The focused laser beam acts as an ignition source and controls the reaction of the oxygen with the metal. In this manner, it is possible to cut the material with a very fine kerf with precision. In order to prevent burning by the beam and/or molten slag on the far wall of the tube I.D., a stainless steel mandrel (approx. 0.034["] inches or 0.8636 mm dia.) is placed inside the tube and is allowed to roll on the bottom of the tube as the pattern is cut. This acts as a beam/debris block protecting the far wall I.D.

Please enter the following substitute paragraph for the specification at page 18, line 4 as follows:

The cutting process utilizing oxygen with the finely focused green beam results in a very narrow kerf (approx. 0.0005["] inches or 0.0127 mm) with the molten slag re-solidifying along the cut. This traps the cut out scrap of the pattern requiring further processing. In order to remove the slag debris from the cut allowing the scrap to be removed from the remaining stent pattern, it is necessary to soak the cut tube in a solution of HCL for approximately 8 minutes at a temperature of approximately 55° C (131° F). Before it is soaked, the tube is placed in a bath of alcohol/water solution and ultrasonically cleaned for approximately 1 minute to remove the loose debris left from the cutting operation. After soaking, the tube is then ultrasonically cleaned in the heated

HCL for 1-4 minutes depending upon the wall thickness. To prevent cracking/breaking of the struts attached to the material left at the two ends of the stent pattern due to harmonic oscillations induced by the ultrasonic cleaner, a mandrel is placed down the center of the tube during the cleaning/scrap removal process. At completion of this process, the stent structure are rinsed in water. They are now ready for electropolishing.

Please enter the following substitute paragraph for the specification at page 18, line 16 as follows:

The stents are preferably electrochemically polished in an acidic aqueous solution such as a solution of ELECTRO-GLO#300, sold by ELECTRO-GLO Co., Inc. in Chicago, Ill., which is a mixture of sulfuric acid, carboxylic acids, phosphates, corrosion inhibitors and a biodegradable surface active agent. The bath temperature is maintained at about 110°-135[0]° F (43°- 57° C). and the current density is about 0.4 to about 1.5 amps per $in.^2$. Cathode to anode area should be at least about two to one. The stents may be further treated if desired, for example by applying a biocompatible coating.

Please enter the following substitute paragraph for the specification at page 19, line 10 as follows:

The stent of the present invention also can be made from metal alloys other than stainless steel, such as shape memory or superelastic alloys. Shape memory alloys are well known and include, but are not limited to titanium, tantalum, nickel titanium and nickel/titanium/vanadium. Any of the superelastic or shape memory alloys can be formed into a tube and laser cut in order to form the pattern of the stent of the present invention. As is well known, the superelastic or shape memory alloys of the stent of the present invention can include the type known as thermoelastic martensitic transformation, or display stress-induced martensite. These types of alloys are well known in the art and need not be further described here.

IN THE CLAIMS:

Please cancel claims 7 and 30.

Please amend claims 1, 2, 17, 21, and 27 as follows:

1. A flexible intravascular stent for use in a body lumen, comprising:

a plurality of cylindrical rings interconnected to form the stent, each cylindrical ring having a first delivery diameter and a second implanted diameter;

each cylindrical ring having a proximal end and a distal end defining a cylindrical wall extending circumferentially between the proximal end and the distal end of the cylindrical ring; and

at least one flexible link attaching each cylindrical ring to an adjacent cylindrical ring, the link including a bounded aperture disposed in the link between [the] adjacent cylindrical rings and disposed nearer one of the ends of the adjacent rings to facilitate mounting of the stent on a delivery device, with the bounded aperture having at least one aperture defining portion disposed generally transverse to the stent longitudinal axis.

2. The stent of claim 1, wherein the bounded aperture comprises two aperture-defining portions generally perpendicular to the stent longitudinal axis.

17. A flexible intravascular stent for use in a body lumen, comprising:

a plurality of cylindrical rings interconnected to form the stent, each cylindrical ring having a first delivery diameter and a second expanded diameter, each cylindrical ring having a plurality of peaks and valleys defining ends of the rings; and

at least one link attaching each cylindrical ring to an adjacent cylindrical ring, the link including (1) an aperture disposed in the link between [the] adjacent

cylindrical rings and also disposed nearer one of the ends of the adjacent rings to facilitate mounting of the stent on a delivery device, (2) an aperture defining link portion disposed generally perpendicular to the stent longitudinal axis, and (3) a tapered portion connecting the link to the generally perpendicular portion.

21. [The stent of claim 20, further comprising a second undulating link portion, wherein the aperture is disposed between the two undulating portions.] A flexible intravascular stent for use in a body lumen, comprising:

a plurality of cylindrical rings interconnected to form the stent, each cylindrical ring having a first delivery diameter, and a second expanded diameter, and a plurality of peaks and valleys; and

at least one link attaching each cylindrical ring to an adjacent cylindrical ring, the link including (1) an aperture disposed in the link between the adjacent cylindrical rings, (2) an aperture defining link portion disposed generally perpendicular to the stent longitudinal axis, (3) a tapered portion connecting the link to the generally perpendicular portion, (4) a radiused portion connecting the tapered and perpendicular

portions, and (5) at least two undulating link portions, one undulating link portion being disposed between the aperture and one ring, and another undulating link being disposed between the aperture and an adjacent ring.

27. A flexible intravascular stent for use in a body lumen, comprising:

a plurality of cylindrical rings interconnected to form the stent, each cylindrical ring having a first delivery diameter and a second expanded diameter;

the cylindrical rings having a plurality of U-shaped portions, Y-shaped portions, and W-shaped portions that are expandable;

each cylindrical ring having a proximal end and a distal end defining a cylindrical wall extending circumferentially between the proximal end and the distal end of the cylindrical ring; and

at least one flexible link attaching each cylindrical ring to an adjacent cylindrical ring, the link including a bounded aperture disposed in a W-shaped portion, the aperture being defined in part by two aperture defining link portions disposed generally perpendicular to the stent longitudinal axis and being connected to the link by two tapered and radiused link portions disposed on opposite sides of the aperture.